



AP32738 066876.0103
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Said I.A. SHALABY et al.
Serial No. : 09/955,877 Examiner : Patten, Patricia A.
Filed : September 19, 2001 Group Art Unit : 1654
For : HERBAL COMPOSITIONS AND TREATMENT METHODS

LETTER ENCLOSING COPIES OF IDS DOCUMENTS

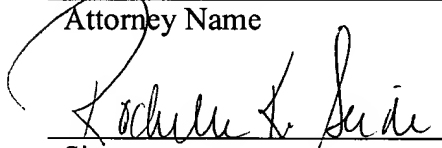
I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MS: Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

May 24, 2004

Date of Deposit

Rochelle K. Seide

Attorney Name


Rochelle K. Seide

Signature

32,300

PTO Registration No.

May 24, 2004

Date of Signature

Mail Stop: Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

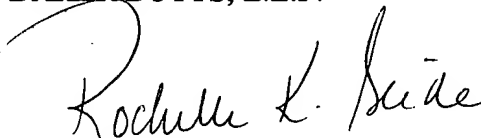
Further to the telephonic interview that Applicant's representatives had with the Examiner on April 14, 2004, Applicants submit herewith copies of the documents cited in the Information Disclosure Statement (IDS) and Form PTO-1449 filed on January 22, 2004. The Examiner indicated that she would mail a Notice of Allowance, but would still consider the documents in Applicants IDS and Form PTO-1449 if copies were expeditiously provided.

Applicants have discovered several minor typographical errors in the IDS and Form PTO-1449 filed on January 22, 2004. Therefore, Applicants have enclosed herewith a marked-up Form PTO-1449 showing the corrections. In addition, to ensure that the cover of any patent issuing from this application correctly cites the documents cited, Applicants have also enclosed a substitute Form PTO-1449 incorporating the corrections. Applicants have further included copies of the January 22, 2004 IDS and Form PTO-1449 for the Examiner's convenience.

While Applicants do not believe any fee is due with this submission, the Commissioner is hereby authorized to deduct any fees required with this submission not otherwise enclosed herewith from Deposit Account No. 02-4377. Two copies of a Fee Transmittal are enclosed.

Respectfully submitted,

BAKER BOTTS, L.L.P.



Rochelle K. Seide
PTO Reg. No. 32,300

Carmella L. Stephens
PTO Reg. No. 41,328
Attorneys for Applicants

Guy F. Birkenmeier
PTO Reg. No. 52,622
Agent for Applicants

BAKER BOTTS L.L.P.
30 Rockefeller Plaza
New York, NY 10112
(212) 408-2500

May 24, 2004

Enclosures



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93

BAKER BOTTS LLP

1654
BPlease type a plus sign (+) inside this box → ☐

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/955,877
Filing Date	September 19, 2001
First Named Inventor	Said I.A. SHALABY et al.
Group Art Unit	1654
Examiner Name	Patten, Patricia A.
Attorney Docket Number	AP32738 066876.0103

Total Number of Pages in This Submission

ENCLOSURES (check all that apply)

- | | | |
|--|---|---|
| <input type="checkbox"/> Fee Transmittal Form
<input type="checkbox"/> Fee Attached
<input type="checkbox"/> Amendment / Reply
<input type="checkbox"/> After Final
<input type="checkbox"/> Affidavits/declaration(s)
<input type="checkbox"/> Extension of Time Request
<input type="checkbox"/> Express Abandonment Request
<input checked="" type="checkbox"/> Information Disclosure Statement
<input type="checkbox"/> Certified Copy of Priority Document(s)
<input type="checkbox"/> Response to Missing Parts/Incomplete Application
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Assignment Papers (for an Application)
<input type="checkbox"/> Drawing(s)
<input type="checkbox"/> Licensing-related Papers
<input type="checkbox"/> Petition
<input type="checkbox"/> Petition to Convert to a Provisional Application
<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address
<input type="checkbox"/> Terminal Disclaimer
<input type="checkbox"/> Request for Refund
<input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Status Letter
<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
See attached sheet |
|--|---|---|

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	BakerBotts LLP 30 Rockefeller Plaza New York, NY 10112	Att Name: Rochelle K. Seide PTO Reg: 32,300
Signature	<i>Rochelle K. Seide</i>	
Date	May 24, 2004	

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on this date: May 24, 2004

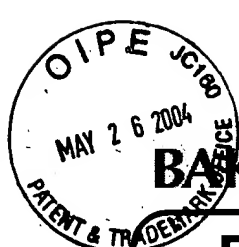
Typed or printed name	Rochelle K. Seide	Date	May 24, 2004
Signature	<i>Rochelle K. Seide</i>		

Title: HERBAL COMPOSITIONS AND TREATMENT METHODS

Use Space Below for Additional Information:

This submission includes:

- Transmittal (2 pages);
- Fee Transmittal (1 sheet in duplicate);
- Letter Enclosing Copies of IDS Documents (2 pages);
- Substitute Form PTO-1449 (3 pages);
- Marked-up Form PTO-1449 (3 pages);
- Copy of previous Form PTO-1449 (3 pages);
- Copy of previous IDS (4 pages);
- Copies of 27 IDS documents (1 bound volume);
- Return Postcard

**BAKER BOTTS LLP**

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27TOTAL AMOUNT OF PAYMENT (\$)**0****Complete if Known**

Application Number	09/955,877
Filing Date	September 19, 2001
First Named Inventor	Said I.A. SHALABY et al.
Examiner Name	Patten, Patricia A.
Art Unit	1654
Attorney Docket No.	AP32738 066876.0103

METHOD OF PAYMENT (check all that apply)☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☐ Deposit Account:Deposit
Account
Number
Deposit
Account
Name

02-4377

Baker Botts LLP

The Commissioner is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Credit any overpayments☐ Charge any additional fee required under 37CFR 1.16 and 1.17☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$)**0****2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

		Extra Claims		Fee from below		Fee Paid	
Total Claims		- 20 =	0	X		=	0
Independent Claims		- 3 =	0	X		=	0
Multiple Dependent							

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)**0**

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for <i>ex parte</i> reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)**0****SUBMITTED BY**

Name (Print/Type)

Rochelle K. Seide

Registration No.
(Attorney/Agent)

32,300

(Complete if applicable)

Telephone 212.408.2500

Signature

Rochelle K. Seide

Date

May 24, 2004

Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark Office

Atty. Docket No.
AP32738 066876.0103

Serial No.
09/955,877

**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

(Use several sheets if necessary)

Applicant
Said I.A. SHALABY et al.

Filing Date
September 19, 2001

Group
1654

U.S. PATENT DOCUMENTS

*Exam. Init.	Document No.	Date	Name	Class	Subclass	Filing Date if Appropriate
	5 8 7 6 7 2 8	03/02/1999	Kass HD et al.			
	5 8 7 4 8 0 4	02/23/1999	Rogers SP			
	5 6 4 8 0 8 9	07/15/1997	Shawkat T			

FOREIGN PATENT DOCUMENT

Document No.	Date	Country	Class	SubClass	Translator Yes No
7 9 3 9 6 4	09/10/1999	Europe (EP)			

OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.)

	Harvard School of Public Health Jan 2004, < http://www.researchmatters.harvard.edu/story.php?article_id=673 >
	Buckwold, Beer, Donis, 2003 "Bovine viral diarrhea as a surrogate model of hepatitis C virus for the evaluation of anti-viral agents" Antiviral Research Vol 60(1):1-15;
	Cost of Developing a New Drug Increases to About \$1.7 Billion By PETER LANDERS, Wall Street Journal December 8, 2003 < http://online.wsj.com/article/0,,SB107083909136415400-email,00.html >
	Abramowicz M, ed., "Enfuvirtide (Fuzeon) for HIV Infection" Med Lett Drugs Ther. 2003 Jun 23; 45(1159): 49-50;
	El-Awady, et al., Clinica Chimica Acta, 283(1-2):1-14 (1999);
	McHutchison et al., "Interferon Alpha-2b Alone or in Combination with Ribavirin as Initial Treatment for Chronic Hepatitis C", New England Journal of Medicine Vol 339 Number 21 November 19, 1998, 1485-1492;

NY02:472768.1

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce
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Yokozawa, et al., J. Traditional Medicine, 15(1):45-51 (1998)

Alter, M.J., Hepatology, 26(1):62S-65S (1997)

Alam, et al., Phytotherapy Research, 10(1):58-61 (1996);

D.S. Chen, J. Formos. Med. Assoc., 95(1):6-12 (1996);

Detre, et al., Viral Hepatitis Rev., 2:219-228 (1996);

D.C. Dale and D.D. Federman, eds., Sci. Amer. Medicine, New York, 4(8):1-10 (1996);

Hibbs, et al., J. Infect. Dis. 168:789-790 (1993);

Lok, et al., Gastroenterology, 105(6):1833-1838 (1993);

Flint SJ et al., Principles of Virology: Molecular Biology, Pathogenesis, and Control, ASM Press, Washington DC, 1990, p.691;

Medicinal Plants of North Africa, Loutfy Boulos, Reference Publications, Inc., pp.150-51 (1983);

Medicinal Plants of North Africa, pp. 74-75, 92-93 (1983);

Bergmeyer and Horder, Clinica Chemica Acta 105:147f-154f (1980);

Encyclopedia of Common Natural Ingredients, Used in Food, Drugs, and Cosmetics, John Wiley & Sons, New York, p.169 (1980);

International Federation of Clinical Chemistry, Scientific Committee, J. Clin. Chem. Clin. Biochem., 18:521-534 (1980);

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Bergmeyer H. U. Methods of Enzymatic Analysis. Verlag Chemic, (1978), pp. 130-135;

Babbar, et al., Ind. J. Exp. Biol., 8:304-312 (1970);

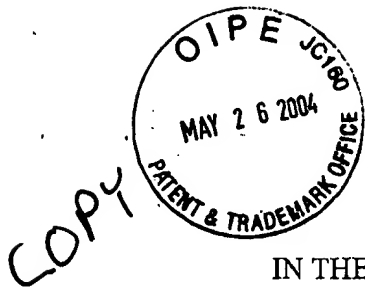
Linus Pauling, General Chemistry, New York, Dover Publications, Inc., 1970, p 744.

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Carmella L. Stephens

Attorney Name

41,328

PTO Registration No.

Carmella L. Stephens
Signature

January 22, 2004

Date of Signature

Commissioner for Patents
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Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 C.F.R. §1.56, Applicant respectfully requests that the documents relating to the above-identified application listed herein in reverse chronological alphabetical order be considered and made of record in the U.S. Patent and Trademark Office.

1. Harvard School of Public Health Jan 2004,

<http://www.researchmatters.harvard.edu/story.php?article_id=673>;

COPY

2. Buckwold, Beer, Donis, 2003 "Bovine viral diarrhea as a surrogate model of hepatitis C virus for the evaluation of anti-viral agents" Antiviral Research Vol 60(1):1-15;
3. Cost of Developing a New Drug Increases to About \$1.7 Billion By PETER LANDERS , Wall Street Journal December 8, 2003
<<http://online.wsj.com/article/0,,SB107083909136415400-email,00.html>>;
4. Enfuvirtide (Fuzeon) for HIV Infection Med Lett Drugs Ther. 2003 Jun 23; 45(1159): 49-50;
5. Abd El-Baset M et al, EP 0793964 published September 10, 1999;
6. El-Awady, et al., Chem. Clinical Acta, 283(1-2):1-14 (1999);
7. Kass HD et al., U.S. Patent No. 5,876,728 issued March 2, 1999;
8. Rogers SP, U.S. Patent No. 5,874,804 issued February 23, 1999;
9. McHutchison et al Interferon Alpha-2b Alone or in Combination with Ribavirin as Initial Treatment for Chronic Hepatitis C, New England Journal of Medicine Vol 339 Number 21 November 19, 1998, 1485-1492;
10. Yokozbawa, et al., J. Traditional Medicine, 15(4):202-207 (1998);
11. Alter, M.J., Hepatology, 26(1):625-655 (1997);
12. Shawkat T, U.S. Patent No. 5,648,089 issued July 15, 1997;
13. Alam, et al., Phytotherapy Research, 10(1):58-61 (1996);
14. D.S. Chen, J. Formos. Med. Assoc., 95(1):6-12 (1996);
15. Detre, et al., Viral Hepatitis Rev., 2:219-228 (1996);
16. D.C. Dale and D.D. Federman, eds. Medicine Sc. Amer., Inc., New York, 4(8):1-8 (1995);
17. Hipps, et al., Infect. Dis. 168:789-790 (1993);

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18. Lok, et al., Gastroenterology, 105(6):1833-1838 (1993);
19. Fields, Virology 2nd ed, New York, Raven Press, 1990 p691;
20. Medicinal Plants of North Africa, Loutfy Boulos, Reference Publications, Inc.,
pp.150-51 (1983);
21. Medicinal Plants of North Africa, pp. 74-75 (1983);
22. Bergmeyer and Horder, Clin. Chem. Acta 105:147 f. (1980);
23. Encyclopedia of Common Natural Ingredients, Used in Food, Drugs, and Cosmetics,
p.169 (1980);
24. International Federation of Clinical Chemistry, Scientific Committee, J. Clin. Chem.
Biochem.,18:521-534 (1980);
25. Bergmeyer H. U. Principles of Enzymatic Analysis. Verlag Chemic, (1978);
26. Babbar, et al., Ind. J. Exp. Biol., 8:304-312 (1970); and
27. Linus Pauling, General Chemistry, New York, Raven Press 1970, p 744.

The referenced citations are listed in the accompanying PTO Form 1449. Copies of the documents will follow as soon as they are available. Identification of the documents listed in the attached PTO Form 1449 is not to be construed as an admission of Applicants or Attorneys for Applicants that such documents are available as "prior art" against the above-identified application.

COPY

Applicants enclose herewith the fees required pursuant to 37 C.F.R. §§ 1.17(p) and 1.97(c)(2). Applicants do not believe any additional fee is due with this submission. Nevertheless, the Commissioner is hereby authorized to deduct any fees required with this submission not otherwise enclosed herewith from Deposit Account No. 02-4377. Two copies of this paper are enclosed.

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